IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Mikhail Vladimirovich KUTUSHOV		
Serial No.:	10/576,039	Group No.:	3761
Filing Date:	14 April 2006	Examiner:	Leslie R. Deak
Title:	SYSTEM FOR CORRECTING BIOLOGICAL FLUID		
Customer No.:	42419		

DECLARATION UNDER 37 CFR 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir,

I, the inventor of this Patent Application and signing below, hereby declare the following in support of my application for Letters Patent in the United States of America:

1. I am the named inventor on U.S. Patent 5,980,479 (the '479 Patent), which has been applied by the Examiner in rejecting this Patent Application under 35 U.S.C. §103.

2. The invention of this Patent Application provides several unexpected benefits over the device of the '479 Patent. Several of these benefits, as best understood at the present time and without wishing to be bound by theory, are explained below.

I hereby certify that this paper is being electronically transmitted to the U.S. Patent and Trademark Office on the date shown below.

Mark D. Saranson
Type or print name of person signing certification

20 May 2009
Date

Signature

3. The mixing of magnetic particles and biological liquids according to the structure of the claimed invention of this Patent Application is more efficient und less traumatic for the biological liquids, and especially for blood, than the device of the '479 Patent.

4. In the device according to the '479 Patent, the flow of biological liquid and magnetic suspension is generally constant, and the contact time between particles and toxins is generally limited in view of the "preservation" of the reacted particles on the surface of the filling material and their agglomeration (clot formation), which does not allow the whole active surface of the paramagnetic particles to react with the toxins.

5. The claimed invention of this Patent Application includes a mixing chamber and the precipitation chamber formed as vessels having one of hard-jointed lids or a mutual lid, a mutual wall fixed to bottoms of the chambers, a mutual wall forming an interchamber partition, inner cavities of the chambers connected through a channel in the interchamber partition, and other side walls of the chambers having corrugations forming corresponding silphons. The chamber lids are fixed on the interchamber partition via hinges with a possibility to rotate around a hinge axis, and the biological fluid flows from the mixing chamber to the precipitation though the channel in the interchamber partition. This recited structure causes the flows of magnetic liquid and biological liquid make periodic stops due to the actions of the bellows-like pumping action. Such periodic stops of the biological liquid containing the magnetic particles promote the efficient collection of toxins. Such structure enables the particles to stay in the main blood flow for a very short time and within a short space of the main. After the sorption, the particles are conducted from the flow into the precipitation tank practically at once.

6. As a comparison of the device of the claimed invention and the device of the '479 Patent, blood from a 19 kg dog was taken from the femoral vein and run through each device within 30 minutes with velocity of 100 ml/min and 1 ml Heparin. The blood coagulation rates upstream of the device and downstream of the device were both measured. The blood coagulation time is the indicator of activity of the blood coagulation

coagulation rates upstream of the device and downstream of the device were both measured. The blood coagulation time is the indicator of activity of the blood coagulation system and equals the time from the blood contact with the foreign surface in vitro till the clot formation. For the device of the '479 Patent, the coagulation time upstream of the device was 12 minutes and downstream of the device was 3 minutes, and the number of platelets were measured at 350 thousand upstream of the device and 320 thousand downstream of the device. For the device according to the invention of Claim 1, the coagulation time upstream of the device was 10 minutes and downstream of the device was 9.5 minutes, and the number of platelets were measured at 340 thousand upstream of the device and 340 thousand downstream of the device.

These examples demonstrate that the claimed invention provided an unexpected increase in coagulation time and a decrease in blood injury.

7. The claimed invention includes an inlet socket simultaneously connected to the inner cavity of each of the mixing chamber and the vessel for the ferreed sorbent. In the invention of dependent Claim 30, the channel from the inlet socket is input into the mixing chamber at an angle of (10-80)° to a bottom plane and, respectively, to the chamber lid and a vertical line. Both the location and the angle at which the blood enters the chamber provide advantages to the flow in the claimed invention. The inlets of the device of the claimed invention of this Patent Application further result in the paramagnetic particles generally having advantageous spatial positions within the separator during the periodic flow stop. According to the claimed invention, the particles having the favorable situation with respect to the liquid flow continue to collect toxins, resulting in a larger amount of the sorption surface being filled up and a better distribution within the separator.

This is an unexpected improvement over the structure of the '479 Patent, in which the separator is filled chaotically with the densest fill at the separator's inlet. This can result in the flow being blocked by large aggregates, which makes the biological liquid flow to stop, thereby threatening vascular embolism and loss of life.

8. As a comparison of the device of the claimed invention and the device of the '479 Patent, blood from a 17 kg dog was taken from the femoral vein and run through each device within 60 minutes with velocity of 100 ml/min and 1 ml Heparin. The volume of the rectangular separator chamber of the '479 Patent device and the elliptical separator chamber of the device of the claimed invention was each 30 ccm. A Phenobarbital (luminal) concentration entering the device inlets was measured at 100 μg/ml. At the outlet of the '479 Patent device, the Phenobarbital concentration was measured at 60 μg/ml. At the outlet of the device of the claimed invention, the phenobarbital concentration was measured at 10 μg/ml. The valve arrangement and structural configuration of the device of the claimed invention thus provided the unexpected result of larger sorption within the chamber. It should be noted, that the appearance of the particles, their amount must be in any case the same.

I further declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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20.05.2009

Date

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